At this point, the practitioner may apply finger pressure to the digital activation surface to downwardly deflect the cantilever and release the shield for movement from the distal position to the proximal position to expose the blade for use. After the use of the blade is complete, the practitioner releases the shield from the proximal position with finger pressure and moves shield 530 to the distal position. The practitioner then grasps the shield, applies distal force and removes the cartridge from the handle for disposal according to the institution's disposal protocol.

What is claimed is:

- 1. A surgical scalpel comprising:
- an elongate handle defining a longitudinal axis and having a proximal end and a distal end;
- a cartridge removably mounted to said handle, said cartridge including a blade holder with a proximal end and a distal end;
- a blade fixedly attached to said blade holder disposed so that said blade projects distally outwardly when said cartridge is mounted to said handle;
- said cartridge including a shield having proximal end, a distal end and a bottom, said shield being mounted onto said blade holder and shield being slidably movable between a distal position wherein said shield substantially prevents inadvertent access to said blade and a proximal position wherein said shield substantially surrounds a portion of said handle and said blade is exposed for use, said cartridge including means for releasably mounting said cartridge to said handle and for substantially preventing said movement of said shield with respect to said blade holder unless said cartridge is mounted on said handle, said cartridge further including at least one means for substantially preventing an inadvertent movement of said shield to said proximal position thereby to expose said blade as said cartridge is being mounted to said handle.
- 2. The surgical scalpel of claim 1 wherein a first means for substantially preventing said inadvertent movement of said shield to said proximal position comprises a first cantilever on said shield extending distally from said proximal end of said shield, said first cantilever having a digital activation section projecting upwardly from a top surface of said shield.
- 3. The surgical scalpel of claim 2 wherein said first means for preventing said movement of said shield with respect to said blade holder further comprises said handle and said blade holder having at least one groove having a distal terminus on said blade holder and a proximal terminus on said handle, said groove extending proximally from said blade holder onto at least a distal portion of said handle, said 50 at least one groove having an upward enlargement at said distal terminus and an upward enlargement at said proximal terminus.
- 4. The surgical scalpel of claim 3 wherein said first means for preventing said movement of said shield between said distal position and said proximal position further includes at least one inwardly projecting boss disposed on first cantilever to engage said at least one groove, said boss projecting into said distal terminus when said shield is in said distal position, said boss projecting into said proximal terminus when said shield is in said proximal position, said shield thereby being normally latched in one of said proximal and distal positions unless said first cantilever is downwardly deflected thereby disengaging said boss from said termina and allowing said slidable movement of said shield between said proximal position and said distal position.
- 5. The scalpel of claim 4 further including means for substantially preventing said cartridge from being mounted

- on said handle when said first cantilever is deflected downwardly, thereby substantially preventing inadvertent exposure of said blade during mounting said cartridge onto said handle.
- 6. The scalpel of claim 5 wherein said means for substantially preventing said cartridge from being mounted on said handle when said first cantilever is being deflected downwardly includes said distal end of said handle being disposed to engage said at least one boss on said cantilever when said first cantilever is downwardly deflected and said cartridge is being mounted to said handle thereby to substantially prevent said cartridge from being mounted on said handle.
 - 7. The scalpel of claim 4 further including means for substantially preventing movement of said shield with respect to said blade holder during mounting said cartridge on said handle when said cartridge is partially properly mounted on said handle and said cantilever is downwardly deflected.
 - 8. The scalpel of claim 7 wherein said means for substantially preventing movement of said shield when said cartridge is partially properly mounted and said cantilever is downwardly deflected includes a recess on said handle disposed distally to said groove to function as a false stop and engage said boss on said cantilever when said cantilever is deflected downwardly substantially to prevent proximal movement of said shield before said cartridge is fully mounted on said handle and thereby to prevent said cartridge from being fully mounted on said handle and prevent movement of said shield from said distal position to said proximal position until said downward deflection of said cantilever ceases.
 - 9. The surgical scalpel of claim 3 wherein said distal upward terminus of said groove in said blade holder further includes a distal surface and a proximal surface each having an upwardmost edge and a lower edge, and wherein said distal upwardmost edge is more distal than said distal lower edge, thereby causing a distal upward pitch to said distal surface, and said proximal upward most edge is more proximal than said proximal lower edge, thereby causing a proximal upward pitch to said proximal surface, to substantially retain said boss in said upward distal terminus until the practitioner applies sufficient direct downward force to said digital activation section to downwardly deflect said first cantilever.
 - 10. The surgical scalpel of claim 9 wherein said proximal terminus and said distal terminus of said groove each further include a roof portion sufficient to substantially prevent upward disengagement of said boss from said termina.
 - 11. The surgical scalpel of claim 10 wherein said blade holder and said handle have one groove on one side and another groove on an opposite side thereof.
 - 12. The surgical scalpel of claim 11 wherein said first cantilever has one boss disposed to engage said one groove on one side of said blade holder and said handle and another boss disposed to engage said second groove on said opposite side of said blade holder and said handle.
 - 13. The surgical scalpel of claim 1 wherein a second means for substantially preventing said proximal movement of said shield as said cartridge is mounted onto said handle comprises a second cantilever on said bottom of said shield, said second cantilever having a distal fixed end and a free proximal end so that if the practitioner inadvertently applies a force to said bottom of said shield as said cartridge is mounted to said handle, said second cantilever is deflected upwardly to engage said blade bolder and substantially prevent inadvertent proximal movement of said shield to expose said blade.
 - 14. The surgical scalpel of claim 1 wherein a third means for substantially preventing inadvertent proximal movement of said shield as said cartridge is mounted to said handle

comprises a finger grip portion on at least one of an outside surface of said shield, said finger grip portion being shaped to facilitate the practitioner's grip for mounting the cartridge onto said handle, thereby substantially preventing the practitioner's inadvertent contact with said digital activation section sufficient to deflect said first cantilever.

15. The scalpel of claim 1 wherein said means for releasably mounting said cartridge on said handle includes a downward projection on said handle and a flexible beam projecting proximally from said blade holder, said beam having a pocket therein for releasably engaging said downward projection on said handle to retain releasably said cartridge on said handle.

16. The scalpel of claim 15 wherein said means for releasably mounting said cartridge on said handle further includes means for substantially preventing said cartridge from being dismounted from said handle unless said shield

is in said distal position.

- 17. The scalpel of claim 16 wherein said means for substantially preventing said cartridge from being dismounted from said handle unless said shield is in said distal position comprises said shield being disposed to prevent substantially said proximally projecting beam on said blade holder from being downwardly deflected and thereby to disengage said downward projection on said handle from said pocket on said beam unless said shield is in said distal position, thereby substantially preventing said pocket in said beam from disengaging from said downward projection on said handle and to retain said cartridge on said handle.
- 18. The scalpel of claim 1 wherein said means to substantially prevent movement of said shield with respect to said blade holder unless said cartridge is mounted on said 30 handle includes a deflectable tab on a side of said shield having an inwardly projecting lug thereon disposed to engage a seat in said blade holder when said shield is in said distal position and said cartridge is not mounted on said handle thereby substantially preventing movement of said shield with respect to said blade holder.
- 19. The scalpel of claim 18 wherein said means for substantially preventing movement of said shield with respect to said blade holder unless said cartridge is mounted on said handle further comprises a distal prong on said handle disposed to engage said tab on said shield when said cartridge is mounted on said handle thereby to disengage said lug from said seat on said blade holder and to permit movement of said shield with respect to said blade holder.

20. The scalpel of claim **19** wherein said distal prong on said handle disposed to engage said tab on said shield further comprises a distal end having a chamfered surface to facilitate said disengagement of said lug from said seat.

- 21. The surgical scalpel of claim 1 wherein said blade is fixedly attached to said outward projection of said blade holder by a bonding selected from the group consisting of 50 heat staking, mechanical cold forming and adhesive bonding.
- 22. The surgical scalpel of claim 1 wherein said blade holder is formed from a thermoplastic material selected from the group consisting of polypropylene, polyethylene, polycarbonate, polysulfone, polyacetal and polyamide.
- 23. The surgical scalpel of claim 1 wherein said shield is formed from a thermoplastic material selected from the group consisting of polypropylene, polyethylene, polycarbonate, polyacetal, and polyamide.

24. The surgical scalpel of claim 1 wherein said shield is formed from a substantially transparent material.

- 25. The surgical scalpel of claim 1 wherein said handle is formed from a material selected from the group consisting of machined metal, formed powdered metal and thermoplastic materials.
- **26.** A cartridge useful for releasably mounting on a handle to form a scalpel comprises:

a blade holder with a proximal end and a distal end;

a blade fixedly attached to said blade holder disposed so that said blade projects distally outwardly when said cartridge is mounted to a handle;

said cartridge including a shield slidably mounted onto said blade holder, said shield being slidably movable between a distal position wherein said shield substantially prevents inadvertent access to said blade and a proximal position wherein said shield substantially surrounds a portion of the handle and said blade is exposed for use, said cartridge further including means to substantially prevent said movement of said shield to said proximal position unless said cartridge is mounted on the handle, to prevent movement of said shield between said proximal position and said distal position. to substantially prevent a dismounting of said cartridge from the handle unless said shield is in said distal position, and means to substantially prevent inadvertent movement of said shield from said proximal position to said distal position as said cartridge is being mounted on said handle.

27. The cartridge of claim 26 being placed in a sealed package formed from materials substantially resistant to the passage of microorganisms and exposed to conditions that render any microorganisms inside said package substantially nonviable.

28. A method for assembling a surgical scalpel having a shielded blade comprises:

providing an elongate handle defining a longitudinal axis and having a proximal end and a distal end;

providing a cartridge including a blade holder with a proximal end and a distal end, said cartridge including a blade fixedly attached to said blade holder disposed so that said blade projects distally outwardly when said cartridge is mounted to said handle, said cartridge further including a shield slidably mounted onto said blade holder, said shield being slidably movable between a distal position wherein said shield substantially prevents inadvertent access to said blade and a proximal position wherein said shield substantially surrounds a portion of said handle and said blade is exposed for use, said cartridge further including means to substantially prevent said movement of said shield to said proximal position unless said cartridge is mounted on said handle, to prevent movement of said shield between said proximal position and said distal position and to prevent substantially a dismounting of said cartridge from the handle unless said shield is in said distal position;

gripping said cartridge at said finger grip portion;

positioning said cartridge so that said proximal end of said cartridge is in substantial axial alignment with said distal end of said handle;

advancing said cartridge proximally onto said distal end of said handle until said cartridge is fully seated thereby forming said scalpel.

29. The method of claim 23 further comprising a method for removing said cartridge from said handle grasping said shield at said finger grip portion; and

applying a distal substantially axial force to said shield sufficient to overcome a resistance to deflect a beam having a pocket on said blade holder and disengage a downward projection on said handle from said pocket on said beam, thereby removing said cartridge from said handle, said distal force serving to move said shield to said distal position in the event that the shield is not in the distal position and allowing said beam to deflect.

* * * * *

Please add new claims 30 – 77 as follows:

- 30. A cartridge that may be mounted on a handle to form a scalpel, comprising:
 - a blade holder with a proximal end, a distal end and an external surface; a blade attached to said blade holder; and
- a shield slidably mounted about said blade holder so as to be disposed about the external surface of the blade holder wherein the shield is movable between a distal position shielding the blade and a proximal position exposing the blade for use.
- 31. The cartridge of claim 30 wherein the cartridge includes a means for releasably mounting said blade holder to a handle.
- 32. The cartridge of claim 31 wherein the proximal end of the blade holder defines a beam with a pocket formed therein for engagement with a handle.
- 33. The cartridge of claim 32 wherein the blade holder includes a medial portion defining a recess therein for engagement with a handle.
- 34. The cartridge of claim 30 further including a latch that positively holds the shield in the distal position.
- 35. The cartridge of claim 34 wherein the latch is a cantilever on the shield.
- 36. The cartridge of claim 34 wherein the blade holder includes a sidewall that defines at least one substantially longitudinally extending groove.

- 37. The cartridge of claim 36 wherein the groove includes a distal end with an upturned stop portion.
- 38. The cartridge of claim 35 wherein the blade holder includes a sidewall that defines at least one substantially longitudinally extending groove and the cantilever includes an inward projection disposed in the groove.
- 39. The cartridge of claim 30 wherein the shield includes means to substantially prevent proximal movement of the shield with respect to the blade holder unless the cartridge is mounted to a handle.
- 40. The cartridge of claim 39 wherein the blade holder includes a seat and the shield includes a tab with an inwardly projecting lug disposed in the seat when the shield is in the distal position.
- 41. The cartridge of claim 30 further including a means to prevent dismounting the cartridge from a handle unless the shield is in the distal position.
- 42. The cartridge of claim 41 wherein the shield defines a proximal portion that substantially surrounds the proximal end of the blade holder.
- 43. The cartridge of claim 32 wherein the shield defines a proximal portion that substantially surrounds the beam when the shield is in the proximal position.
- 44. The cartridge of claim 30 wherein the shield includes at least one finger placement surface with a discrete surface configuration that facilitates gripping of the shield by a clinician.
- 45. A cartridge that may be mounted on a handle to form a scalpel. comprising:

- a blade holder with a proximal end and a distal end;
- a blade attached to said blade holder;
- a shield slidably mounted on said blade holder for movement between a distal position shielding the blade and a proximal position exposing the blade for use; and
 - a means for releasably mounting said blade holder to a handle.
- 46. The cartridge of claim 45 wherein the proximal end of the blade holder defines a beam with a pocket formed therein for engagement with a handle.
- 47. The cartridge of claim 46 wherein the blade holder includes a medial portion defining a recess therein for engagement with a handle.
- 48. The cartridge of claim 45 further including means that substantially prevents dismounting of the cartridge from a handle unless the shield is in the distal position.
- 49. The cartridge of claim 45 wherein the shield defines a proximal portion that substantially surrounds the beam when the shield is in the proximal position.
- 50. The cartridge of claim 45 wherein the shield includes at least one finger placement surface with a discrete surface configuration that facilitates gripping of the shield by a clinician.
- 51. A cartridge that may be releasably mounted on a handle to form a scalpel, comprising:
 - a blade holder with a proximal end and a distal end; a blade attached to said blade holder;

a shield slidably mounted on said blade holder so as to be movable between a distal position substantially surrounding the blade and a proximal position exposing the blade for use; and

a latch that substantially prevents proximal movement of the shield with respect to the blade holder unless the cartridge is mounted to a handle.

- 52. The cartridge of claim 51 wherein the blade holder includes a seat and the shield includes a tab with an inwardly projecting lug disposed in the seat when the shield is in the distal position.
- 53. The cartridge of claim 51 wherein the shield includes at least one finger placement surface with a discrete surface configuration that facilitates gripping of the shield by a clinician.

54. A surgical scalpel, comprising:

a handle defined by a pair of sidewalls having at least one external surface and having a proximal portion and a distal portion wherein at least one sidewall includes a groove formed in the external surface and extending substantially longitudinally along the distal portion of the handle;

a blade attached to the handle adjacent to the distal portion of the handle;
a shield slidably mounted to the handle along the distal portion of the
handle so as to be movable between a distal position shielding the blade and a
proximal position exposing the blade for use; and

a latch associated with the shield and having an inward projection disposed in the groove to releasably hold the shield in the distal position and the proximal position.

55. The surgical scalpel of claim 54 wherein the groove includes an upturned proximal end and an upturned distal end and the latch is cantilevered to be biased upwardly.

- 56. The surgical scalpel of claim 55 wherein the latch snaps into the upturned proximal end of the groove to indicate that the shield is locked in the proximal position and the latch snaps into the upturned distal end of the groove to indicate that the shield is locked in the distal position.
- 57. The surgical scalpel of claim 54 wherein the shield includes at least one finger placement surface with a discrete surface configuration that facilitates gripping of the shield by a clinician.
- 58. The surgical scalpel of claim 54 wherein the distal portion of the handle defines a top cut-away portion extending along the length of the groove to facilitate movement of the latch.
- 59. The surgical scalpel of claim 58 wherein the top cut-away portion extends between two end portions having a raised upper surface.
- 60. The surgical scalpel of claim 54 wherein the shield includes at least one inwardly projecting rail and the handle includes at least one slot formed in the external surface and extending substantially along the distal portion of the handle such that the inwardly projecting rail is disposed in the slot to facilitate movement of the shield between the distal position and the proximal position.
- 61. The surgical scalpel of claim 54 wherein the shield covers a proximal portion of the blade when the shield is in the proximal position exposing the blade for use.
- 62. A handle that may be mounted on a cartridge to form a scalpel, comprising:

a proximal hand gripping portion having a distal end;

an intermediate shank having a proximal end and a distal end connected at its proximal end to the distal end of the proximal hand gripping portion;

a tang extending from a distal end of the intermediate shank; and a means for releasably connecting the handle to a cartridge.

- 63. The handle of claim 62 further comprising a downwardly extending projection formed in the intermediate shank.
- 64. The handle of claim 62 wherein the intermediate shank includes an outer surface defining a substantially longitudinally extending groove.
- 65. The handle of claim 64 wherein the groove includes an upturned portion.
- 66. The handle of claim 62 wherein the tang defines a recess disposed therein.

67. A surgical scalpel, comprising:

a handle having a proximal hand gripping portion having a distal end, an intermediate shank having a proximal end and a distal end connected at its proximal end to the distal end of the proximal hand gripping portion wherein the intermediate shank defines a substantially longitudinally extending groove therein, and a tang extending from a distal end of the intermediate shank;

a cartridge releasably mounted on the handle to form a scalpel including a blade holder with a proximal end and a distal end and a blade attached to said blade holder wherein the blade holder defines a substantially longitudinally extending groove therein aligned with the groove formed in the intermediate shank; and

a shield slidably mounted about the cartridge so as to be movable between a distal position shielding the blade and a proximal position exposing the blade for use and having a latch associated with the shield and having an inward projection disposed in the groove to releasably hold the shield in the distal position and the proximal position.

- 68. The surgical scalpel of claim 67 wherein the blade holder defines a beam with a pocket formed therein for engagement with the handle.
- 69. The surgical scalpel of claim 68 further including a projection extending downwardly from the intermediate shank for engagement with the pocket formed in the beam.
- 70. The surgical scalpel of claim 68 wherein the shield defines a proximal portion that substantially surrounds the beam when the shield is in the proximal position.
- 71. The surgical scalpel of claim 67 wherein the groove includes an upturned proximal end and an upturned distal end and the latch is cantilevered to be biased upwardly.
- 72. The surgical scalpel of claim 71 wherein the latch snaps into the upturned proximal end of the groove to indicate that the shield is locked in the proximal position and the latch snaps into the upturned distal end of the groove to indicate that the shield is locked in the distal position.
- 73. The surgical scalpel of claim 67 wherein the shield includes at least one finger placement surface with a discrete surface configuration that facilitates gripping of the shield by a clinician.
- 74. The surgical scalpel of claim 67 wherein the distal portion of the handle defines a top cut-away portion extending along the length of the groove to facilitate movement of the latch.
- 75. The surgical scalpel of claim 74 wherein the top cut-away portion extends between two end portions having a raised upper surface.

- 76. The surgical scalpel of claim 67 wherein the shield includes at least one inwardly projecting rail and the handle includes at least one slot formed in the external surface and extending substantially along the distal portion of the handle such that the inwardly projecting rail is disposed in the slot to facilitate movement of the shield between the distal position and the proximal position.
- 77. The surgical scalpel of claim 67 wherein the shield covers a proximal portion of the blade when the shield is in the proximal position exposing the blade for use.

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